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Datasheet for the decision of 22 April 2009

Case Number: T 1718/06 - 3.2.02

Application Number: 00973499.7

Publication Number: 1248569

IPC: A61B 17/22

Language of the proceedings: EN

Title of invention:
Needle-less injection apparatus and method

Applicant:
Boston Scientific Limited

Headword:
-

Relevant legal provisions:
EPC Art. 56

Relevant legal provisions (EPC 1973):
-

Keyword:
"Inventive step (no)"

Decisions cited:
-

Catchword:
-

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Case Number: T 1718/06 **-** 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 22 April 2009

Appellant: Boston Scientific Limited
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 27. June 2006 refusing European application No. 00973499.7 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: M. Noel
Members: D. Valle
M. J. Vogel

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal on 29 August 2006 against the decision of the examining division posted on 27 June 2006 to refuse the application on the basis of Articles 123 (2) and 56 EPC. The fee for the appeal was paid on the same day and a statement setting out the grounds for appeal was received on 30 October 2006.

II. The following document is relevant for the present decision:

D1 = WO - A - 9949926.

III. Oral proceedings were held on 22 April 2009, at the end of which the appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 17 in the version of the main request, or in the version of one of the auxiliary requests I to IV, all filed during the oral proceedings.

IV. Claim 1 of the main request reads as follows:

"A catheter system for delivering and injecting a fluid into heart tissue (60), comprising:
a pressurized fluid source (20) containing a fluid therein, the pressurized fluid source generating a high transient pressure in excess of 27,6 MPa, sufficient to pierce bodily tissue; and
an injection catheter (24) including an elongate shaft (14) having a proximal end, a distal end and an infusion lumen extending therein,

the proximal end of the shaft (14) connected to the pressurized fluid source (20),
the infusion lumen in fluid communication with the fluid contained in the pressurized fluid source (20), the distal end of the shaft (14) including a nozzle (26) having an injection port (30) in fluid communication with the infusion lumen such that fluid from the pressurized fluid source (20) may be delivered to the heart tissue via the infusion lumen of the shaft (14) and the injection port (30) at the sufficient exit velocity to partially penetrate the heart tissue."

Claim 1 of the first auxiliary request differs from the content of the main request in that the feature "in less than one second" has been added after the words "in excess of 27,6 MPa" and in that the feature "to reduce leakage from the injection site" has been added at the end of the claim.

Claim 1 of the second auxiliary request differs from the content of the first auxiliary request in that the feature "less than 100 µl of" has been added before the words "fluid from the pressurized fluid source (20)" in the last part of the claim.

Claim 1 of the third auxiliary request differs from the content of the second auxiliary request in that the feature "a sheath having a stabilizing means" has been added after the second group of features: "A pressurized fluid source (20)... tissue;", and in that the feature "the injection catheter (24) slidable within the sheath (28)" has been added after the third group of features: "an injection catheter (24) ... therein,".

The fourth auxiliary request differs from the content of the third auxiliary request in that the feature: "and the distal end of the catheter being extendable past the stabilizing face of the sheath (28)" has been added after the words "slidable within the sheath (28)".

V. The appellant argued essentially as follows:

The injection device of the invention was specifically designed for delivering and injecting agents in the myocardium which harmed the heart tissue less in comparison to known techniques and which made the agents rest in the myocardium. This aim was achieved by applying a very high pressure in excess of 27,6 MPa in a very short time. In contrast to that, in the device according to D1 which is regarded as the closest prior art, an agent was introduced into the heart tissue by dissecting and disrupting tissue so as to form a channel 169 (Figures 16A and 16B), thereby creating large wounds. Moreover, the acting fluid was not even the therapeutic agent as taught by the present invention.

The auxiliary requests contained additional functional and structural features which further specified the invention and which were not made obvious by the available prior art.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request - Inventive step*

Using the terms of claim 1 in suit, document D1 (see Figures 1 and 16A, 16B) discloses a catheter system for delivering and injecting a fluid into heart tissue, comprising a pressurized fluid source 10 containing a fluid therein, the pressurized fluid source generating a high transient pressure sufficient to pierce bodily tissue (see from page 27, line 18 to page 28, line 7) and an injection catheter 160 including an elongated shaft having a proximal end, a distal end and an infusion lumen extending therein, the proximal end of the shaft being connected to the pressurized fluid source and the infusion lumen being in fluid communication with the fluid contained in the pressurized fluid source. Further, the distal end 164 of the shaft (Figure 16A) includes a nozzle having an injection port (for emitting a jet of fluid 162) in fluid communication with the infusion lumen of the shaft such that fluid from the pressurized fluid source may be delivered to the heart tissue via the infusion lumen of the shaft and the injection port at the sufficient exit velocity to partially penetrate the heart tissue (see the above quoted passage).

D1 differs from the subject-matter of claim 1 in that it does not disclose that the pressure applied is in excess of 27,6 MPa. With respect to D1, the objective problem underlying this distinguishing feature is, therefore, to adjust the high pressure to a value

sufficient to achieve the result as claimed. As mentioned in the present application (see page 9, lines 10 - 18) the penetration depth of the fluid depends on the exit velocity which, in turn, depends on the applied pressure as required by the particular application. The same is disclosed in D1 (last line of page 27).

The choice of a suitable pressure for the jet of fluid to partially penetrate the heart tissue is considered, however, to be the result of a workshop activity involving no more than trial-and-error experimentation without any inventive skill.

The argument of the appellant that the apparatus of the invention advantageously does not disrupt the tissues of the heart and does not form a channel caused by the penetration of the distal tip, in contrast to the case of the device disclosed in D1, is not convincing for the following reasons.

D1 generally discloses with reference to Figures 16A and 16B a solution in which a dose of an angiogenic substance is injected axially (see page 27, line 5) through a jet of fluid 162, which is forced out at a sufficient velocity and pressure to disrupt the heart tissue and possibly to form a channel 169 (see top of page 28). When, however, this technique is applied to transmyocardial revascularization (TMR) following a percutaneous approach (PMR) (see D1, page 4, lines 3 - 9), which is the minimally invasive approach also used in the present application, the energy applied by the fluid is limited and no channel is formed. In this case the energy is used only to inject a dose

("uptake") of angiogenic agent which partially ("locally") penetrates the tissue (see D1, page 32, lines 7 - 15). This alternative is similar to the use and the results achieved by the injection device of the present application and illustrated by Figure 7c.

Accordingly, the subject-matter of claim 1 of the main request does not involve an inventive step within the meaning of Article 56 EPC.

3. *Auxiliary requests*

3.1 First auxiliary request

The additional feature "in less than one second" represents the duration at which pressure shots are generated by the pressurized fluid source (application, page 6, line 12). Like the pressure or the velocity, the duration of the pressure pulses belongs to the parameters which are to be adjusted by the skilled person at need, without the exercise of any inventive contribution. Moreover, such parameter adjustments relate to the use of the device and do not structurally distinguish the claimed device from the device of D1. Also in D1 a "dose" of agent is forced out of the catheter (see page 27, line 23), which necessarily implies a short duration.

The additional feature "to reduce leakage from the injection site" fails to add any inventive contribution to the subject-matter of claim 1. The person skilled in the field is certainly aware that it is desirable, if only for reasons of economy, to have the fluid delivered possibly without leakage and as precisely as

possible to the desired area of the heart. The same is true with the delivery system of D1, the aim of which is also to increase the retention of the agent at the injection site (see D1, page 32, line 14-15: "while enhancing the uptake").

3.2 Second auxiliary request

The additional feature "less than 100 µl of" (fluid) refers to a small volume of the injected agent. Likewise, a "dose" is referred to in D1 and the selection of an appropriate volume is only a matter of choice depending, like the other above-mentioned parameters, on the particular clinical application. The additional feature, therefore, does not add anything inventive to the claimed subject-matter.

3.3 Third and fourth auxiliary requests

The additional feature "a sheath (28) having a stabilizing means" is clearly suggested by an alternative embodiment (not illustrated) disclosed in D1 (see page 25, lines 1 - 5), according to which a vacuum or suction device is provided to adhere the distal end of the catheter to the tissue. The stabilizing means is then formed by the space between multiple catheters and the vacuum is applied so as to fix the device in place by suction.

The additional features "the injection catheter (24) slidable within the sheath (28)" and "the distal end of the catheter being extendable past the stabilizing face of the sheath (28)" are both suggested by D1 in reference to Figure 7 and the text referred to. The

catheter represented in Figure 7 is clearly movable and protrudes beyond the sheath or sleeve 28. These constructional features are anyway regarded as close at hand for a person skilled in the art and without inventive significance. Moreover, it should be noted that the second feature mentioned above, and in particular a stabilizing "face" are not supported by the application as filed and can be ignored for the comparison with the prior art.

Accordingly, the subject matter of all claims 1 of the first to fourth auxiliary requests do not involve an inventive step, either.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Sauter M. Noël